

Common Drug Review (CDR) Submission Requirements for Fixed Dose Combinations

To support the tailored review process for fixed dose combination products containing two or more drugs already funded by the CDR-participating drug plans, the submission requirements are being modified. The main changes are in section 4.2 Submission Requirements for New Drugs, New Combination Products, and Drugs with New Indications (beginning on page 8) of the July 2009 version of the [Common Drug Review Submission Guidelines for Manufacturers](#). **Specifically, section 4.2(e) Efficacy, Effectiveness, and Safety Evidence, and section 4.2(f) Economic and Epidemiologic Information are being replaced by the following requirements:**

e) Supporting Evidence for the Fixed Dose Combination

- A completed template containing the following information supported by references:
 - Rationale for the combination: pharmacologic and therapeutic rationale
 - Bioequivalence
 - A copy of the Health Canada Reviewers' Report (also called Pharmaceutical Safety and Efficacy Assessment) including the section demonstrating bioequivalence of the fixed dose combination with the individual components
 - Pharmacokinetic Information
 - the place in therapy of the combination
 - harms information for combination, components and comparators
 - cost information
 - budget impact analyses, must be provided as a Category 1 requirement **if a Priority Review** based on cost savings is requested.
 - copies of references cited in support of evidence provided in this section
- A copy of one clinical study using the fixed dose combination in question (not the individual components) must be supplied. It can be a pharmacokinetic study.